60th Medical Group (AMC), Travis AFB, CA

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20170005A **DATE:** 9 March 2018

PROTOCOL TITLE: Determining the Cardiovascular Effect of Partial versus Complete REBOA in a Porcine (*Sus scrofa*) Model of Hemorrhagic Shock.

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Capt Emily Tibbits

DEPARTMENT: SGSE **PHONE #:** 937-901-6095

INITIAL APPROVAL DATE: 3 January 2017 **LAST TRIENNIAL REVISION DATE:** N/A

FUNDING SOURCE: HMJ

1. RECORD OF ANIMAL USAGE:

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
Sus scrofa	**30**	**16**	**16**

2. PROTOCOL TYPE / CHARACTERISTICS: (Check all applicable terms in **EACH** column)

___ Training: Live Animal ___ Medical Readiness ___ Prolonged Restraint

___ Training: non-Live Animal ___ Health Promotion ___ Multiple Survival Surgery

___ Research: Survival (chronic) ___ Prevention ___ Behavioral Study

_X_ Research: non-Survival (acute) ___ Utilization Mgt. ___ Adjuvant Use

___ Other ( ) ___ Other (Treatment) ___ Biohazard

3. PROTOCOL PAIN CATEGORY (USDA): (Check applicable) ___ C _X_ D ___ E

4. PROTOCOL STATUS:

***Request Protocol Closure:**

___ Inactive, protocol never initiated

___ Inactive, protocol initiated but has not/will not be completed

_X_ Completed, all approved procedures/animal uses have been completed

5. Previous Amendments:
List all amendments made to the protocol.. **IF none occurred, state NONE. Do not use N/A.**

For the Entire Study Chronologically

Amendment Number	Date of Approval	Summary of the Change
1	11 Jan 17	Animal Use, Procedures
2	20 Feb 17	Personnel
3	6 Mar 17	Procedures

6. FUNDING STATUS: Funding allocated: $24,600 Funds remaining: $0

7. PROTOCOL PERSONNEL CHANGES:

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review? _X_ Yes ___ No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

ADDITIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

Col Jeremy Cannon- AI – Yes, Mr. Steven Chu (AI) – Yes

DELETIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

None

8. PROBLEMS / ADVERSE EVENTS: Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

We had to exclude three animals from our study due to technical errors on the part of the investigators. These events were reported to the IACUC.

9. REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:

REPLACEMENT (ALTERNATIVES): Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

No

REFINEMENT: Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

No.

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

No.

10. PUBLICATIONS / PRESENTATIONS: (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

None yet.

11. PROTOCOL OBJECTIVES: (Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?)

Yes, the protocol objectives were met. While data analysis is still underway, the results from this study will make a significant contribution to the REBOA literature and address important questions regarding applicability of REBOA in different positions for different therapeutic goals. This will, in turn, help to guide the practice of those providing resuscitative care to our critically injured service-members.

12. PROTOCOL OUTCOME SUMMARY: (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

Objectives: Endovascular Variable Aortic Control (EVAC) is one strategy in development to mitigate adverse effects of REBOA. The impact of endovascular aortic occlusion specifically on cardiac performance remain not well described in the literature. The objective of this study was to characterize, quantify, and compare the effects of REBOA and EVAC on cardiac function.

Methods: Eighteen swine underwent controlled hemorrhage of 25% blood volume, followed by 45 minutes of either Zone 1 REBOA, EVAC, or no intervention (control). Balloon volume in the EVAC arm was titrated to maintain aortic flow (AF) of 300 mL/min. Animals were then resuscitated with shed blood, intra-aortic balloons were deflated, and five hours of critical care ensued prior to euthanasia. Cardiac function was measured continuously with a Scisense Pressure-Volume Catheter (Transonic Systems Inc.) placed in the left ventricle under fluoroscopic guidance. Physiologic parameters were recorded continuously.

Results: There were no differences in physiology at baseline or during the initial 30 minutes of hypotension. There were no differences in cardiac output at the start of experiment (REBOA 5.3±3.6 L/min versus EVAC 4.1±1.4 L/min, p=0.39) or at the end of the 30 minute bleed period (REBOA 5.7±1.9 L/min versus EVAC 5.9±1.9 L/min, p=0.81). During the intervention period there were no differences in average cardiac output (REBOA 11.5±4.5 L/min versus EVAC 7.5±2.8 L/min, p=0.09) or in the maximal cardiac output (REBOA 14.5±5.3 L/min versus EVAC 9.3±3.1 L/min, p=0.08). During the critical care phase of the experiment, REBOA animals had a higher cardiac output (10.2±5.3 L/min) when compared to EVAC animals (6.2±2.9 L/min, p=0.02).

Conclusions: This study demonstrates that although EVAC does not change the cardiac output required during the intervention, EVAC does allow for a lower cardiac output during critical care when compared to complete REBOA.

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15 Mar 2018

EMILY TIBBITS, Capt, USAF, MC
Primary Investigator

Date

Attachments:
Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission **(Mandatory)**

Attachment 1
Defense Technical Information Center (DTIC) Abstract Submission

This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

Objectives: The objective of this study was to characterize, quantify, and compare the effects of REBOA and Endovascular Variable Aortic Control (EVAC) on cardiac function.

Methods: Eighteen swine underwent hemorrhage of 25% blood volume, followed by 45 minutes of REBOA, EVAC, or no intervention (control). Balloon volume in the EVAC arm was titrated to maintain aortic flow (AF) 300 mL/min. Animals were resuscitated with shed blood, intra-aortic balloons were deflated, and five hours of critical care ensued prior to euthanasia. Cardiac function was measured continuously with a Scisense Pressure-Volume Catheter (Transonic Systems Inc.) in the left ventricle.

Results: There were no differences in cardiac output at the start of experiment (REBOA 5.3±3.6 L/min versus EVAC 4.1±1.4 L/min, p=0.39) or at the end of the 30 minute bleed period (REBOA 5.7±1.9 L/min versus EVAC 5.9±1.9 L/min, p=0.81). During the intervention, there were no differences in average cardiac output (REBOA 11.5±4.5 L/min versus EVAC 7.5±2.8 L/min, p=0.09) or maximal cardiac output (REBOA 14.5±5.3 L/min versus EVAC 9.3±3.1 L/min, p=0.08). During critical care, REBOA animals had higher cardiac output (10.2±5.3 L/min) compared to EVAC animals (6.2±2.9 L/min, p=0.02).

Conclusion: This study demonstrates that although EVAC does not change the cardiac output required during the intervention, EVAC does allow for lower cardiac output during critical care when compared to complete REBOA.

Grant Number:_____
From:_____
****If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**